DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0379]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Preparing a Claim of Categorical Exclusion or an Environmental Assessment for Submission to the Center for Food Safety and Applied Nutrition

FDA's regulation in 21 CFR 25.20 specifies the types of actions related to food additive petitions, color additive petitions, requests for exemption from regulation as a food additive under § 170.39 (21 CFR 170.39), notifications for food contact substances under section 409(h) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(h)), generally recognized as safe (GRAS) affirmation petitions, and citizen petitions for certain food labeling regulations that require at least the preparation of an environmental assessment (EA), unless the action qualifies for a categorical exclusion under 21 CFR 25.30 or 25.32. FDA's regulations in part 25 (21 CFR part 25) are based upon the requirements of the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*). The agency's collection of information on food additives and food-contact substances is based upon the requirements in section 409 of the act. Likewise, section 721 of the act (21 U.S.C. 379(e)) provides for the collection of information on color additives. The submission to FDA by interested parties of a GRAS affirmation petition is voluntary. The information to be submitted with a GRAS affirmation petition is listed in §170.35 (21 CFR 170.35), including, in § 170.35(c)(1)(viii), the environmental information to be submitted. The environmental information to be submitted with petitions for certain food labeling regulations is listed in 21 CFR 101.12(h)(12) and 101.69(h) and in paragraph F of the form for petitions for a health claim in 21 CFR 101.70(f).

Thus, FDA collects information on the potential for environmental impacts of its actions in the form of environmental assessments and claims for categorical exclusions from interested parties who request agency action by submitting to the agency any of the above listed petitions, requests for exemption, or food contact substance notifications. After this information has been collected, the agency will use it to determine whether its action may significantly affect the quality of the human environment.

FDA has collected information from interested parties requesting agency action for many years. Over the years, this collected information has taken several different forms. The agency amended its environmental regulations in the 1997 rule to reduce the number of NEPA evaluations by providing for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant affect on the quality of the human environment. In the 1997 rule, FDA also removed the formats for EAs from its regulations and, instead, now directs interested parties to the agency's centers for information on what is needed in EAs. This draft guidance is FDA's current thinking on what information is needed for the environmental documentation of the actions that are most often requested. The draft guidance contains requests for certain information that has not been requested routinely in the past. FDA is now requesting that submitters provide certain information to support their claims that the categorical exclusions listed in §25.32(i), (o), and (q) will be applicable to their requested actions. Since these informational requests are new, FDA is requesting approval from OMB for this collection of information. The remainder of the environmental information requests are covered by the information collection approvals for the underlying actions, i.e., the OMB control number for food additive petitions is 0910–0016; for color

additive petitions, 0910–0185; for requests for exemption from regulation as a food additive under § 170.39, 0910–0298; for notifications for food contact substances, 0910–0480; for GRAS affirmation petitions, 0910–0132; and for petitions for food labeling regulations, 0910–0183.

Description of Respondents: The likely respondents include businesses engaged in the manufacture or sale of food, food ingredients, and substances used in materials that come into contact with food.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
25.32(i)	68	2	136	1	136
25.32(o)	1	1	1	1	1
25.32(q)	5	2	10	1	10
Total					147

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The above estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for §25.32(i) and (q) that the agency has received since its environmental regulations were amended to include additional categorical exclusions. Please note that, since the agency revised its environmental regulations, there have been no submissions that requested an action that would have been subject to the categorical exclusion in §25.32(o). To avoid counting this burden as zero, we have estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission. The hours per response values were estimated as follows: First, we assumed that the new information requested in this guidance for each of these three categorical exclusions is readily available to the submitter. For the new information requested for the exclusion in §25.32(i), we expect that submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for attachment to the claim for categorical

exclusion. We believe that this effort should take no longer than 1 hour per submission. For the new information requested for the exclusions in §25.32(o) and (q), the submitters will almost always merely need to copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should also take no longer than 1 hour per submission.

Dated: March 2, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S